Operating Instructions
OS3 Vitrex VC830201

VV016031E

0297

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1 Application and description

The OS3 Vitrex operating unit is used for surgical procedures in the posterior segment of the eye. It can be used as a stand-alone unit or, preferably, in conjunction with the OS3 VC830100 base unit.
The functional features offered by the instrument include inter-ocular lighting, an air pump to maintain inner eye pressure and a pump for the injection and extraction of visco-elastic substances.

The unit actuates and controls the accompanying instrumentation and consumable materials within the performance limit values selected by the operator in each case, and as set on the control panel. A foot pedal is used for the fine adjustment of these values within the specified range. The unit is extremely easy to operate. Frequently used settings can be stored and recalled.

The unit may only be used with the Oertli instruments and consumable materials recommended and supplied by the manufacturer (see Section 11).

The unit may only be operated by trained personnel. The surgeon is responsible for defining the correct settings.

The unit is not suitable for surgical interventions outside the eye. If in doubt, please contact the manufacturer.

2 Important points and hazards

IMPORTANT!

Please read these instructions very carefully before using the apparatus for the first time!

IMPORTANT!

The user is responsible for ensuring compliance with and fulfilment of IEC 60601-1

IMPORTANT!

Before connecting the unit, check that the voltage shown on the rating plate is the same as that of the operating room!

CAUTION!

The Visco instrument connections (INJCT and EXTR) must never come into direct contact with the eye! If a syringe is to be used as a silicone container, care must be taken to ensure that there is no air in the syringe reservoir!

IMPORTANT!

While in the EXTR mode, ensure that liquid is never sucked into the unit at the Visco instrument connection, especially during the application of substances with a lower viscosity.

IMPORTANT!

The correct choice of equipment settings is the responsibility of the surgeon!
Settings given in this instruction manual are suggestions only.

IMPORTANT!

Only those instruments and accessories supplied by the manufacturer and listed in Section 11 may be used!

IMPORTANT!

Alterations and repairs may only be undertaken by persons authorised by the manufacturer, otherwise the proper functioning of the unit may be impaired.

CAUTION!

The unit must never be used in areas containing inflammable anaesthetics!

IMPORTANT!

When setting up the unit, ensure that neither the rear ventilation holes nor the top of the unit are covered.

CAUTION!

Never look directly into the lamps when they are lit!

IMPORTANT!

Mobile telephones and other appliances that use radio frequencies may cause unexpected or undesirable behaviour of the unit or system!

IMPORTANT!

Never place the unit or system next to or on top of other appliances when operating it. If it is necessary to arrange the appliances in this way, it must be checked in each case that the unit or system is working correctly.

NOTE!

In order to avoid the risk of electric shock, this unit may only be connected to mains supplies with a protective earth connection.

The control panel

All settings for operating the OS3 Vitrex unit can be entered on the control panel (pre-settings are entered in ParaProg, see Section 7). A visual display shows at a glance the operating state of the system and the current values.
The buttons respond to gentle pressure which can also be applied either with a sterile swab or the sterile operating pen (VE850003) available from the manufacturer.

Depending on the stage of the operation or the position of the control pedal, certain buttons will be disabled. This feature offers increased protection against improper use.

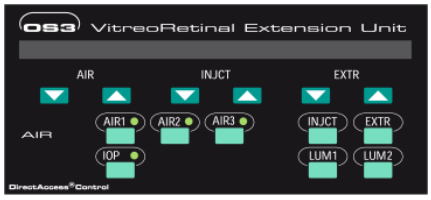
The execution of a command is accompanied by corresponding changes in the display field. If a disabled button is pressed, no change is shown on the display.

The control panel cannot be separated from the unit. If you are using it in combination with the OS3 VC830100 base unit, a VE830020 remote controller can be attached.

2.1 Arrangement of control and indicator elements

Diplay and setting area

Function selection area



The control and indicator elements are grouped in such a way that they can be operated after only a short period of familiarisation, even in semi-darkness. The top half of the control panel is the indicator and setting area. It is designed to show at a glance the operating state of the unit and the current values. The values displayed can be increased or reduced using the dark green arrow buttons directly below the value displays.
The lower half of the control panel houses the function selection buttons.

Please familiarise yourself thoroughly with this ergonomic arrangement of the control elements; it will enable you to operate the equipment quickly almost "blind"!

The display and setting area

Air pressure indicator

Injection pressure indicator

Extraction vacuum Indicator

Air pressure indicator
Displays the selected limit value (current value flashes when active) of the air pressure at the AIR (A) outlet. The unit of measurement can be set using ParaProg (mmHg, PSI, kPa).

Injection pressure indicator
Displays the selected limit value (current value flashes when active) of the injection pressure at the VISCO (B) outlet. The unit of measurement can be set using ParaProg (mmHg, PSI, kPa).

Extraction vacuum indicator
Displays the selected limit value (current value flashes when active) of the extraction vacuum at the VISCO (B) outlet. The unit of measurement can be set using ParaProg (mmHg, PSI, kPa).

Arrow buttons
The arrow buttons can be used to reduce (down arrow) or increase (up arrow) the value shown in the display field immediately above. Exert normal pressure to change the value slowly or in individual increments, or fully depress for rapid value setting.

The function selection area

AIR1 button and indicator light
Activates the AIR function with the pressure value stored in memory 1. The indicator lamp lights up.
Press again to activate the pump and reduce pressure. Pressing once more will deactivate the pump and the function and switch off the indicator lamp.

AIR2 button and indicator light
Activates the AIR function with the pressure value stored in memory 2. The indicator lamp lights up.
Press again to activate the pump and reduce pressure. Pressing once more will deactivate the pump and the function and switch off the indicator lamp.

AIR3 button and indicator light
Activates the AIR function with the pressure value stored in memory 3. The indicator lamp lights up.
Press again to activate the pump and reduce pressure. Pressing once more will deactivate the pump and the function and switch off the indicator lamp.

INJCT button
Activates the Visco injection function with the limit value last used for the injection pressure. Press again to switch off the function.

EXTR button
Activates the Visco extraction function with the limit value last used for the extraction vacuum. Press again to switch off the function.

IOP button and indicator light
Enables the control of AIR functions via a duallinear pedal (illuminated display) when operated in combination with the OS3 VC830100 base unit
When the unit is operated in stand-alone mode this button has no function.

LUM1 button
Switches the left-hand light source (LUM1) on and off.

LUM2 button
Switches the right-hand light source (LUM2) on and off.

Note: If the light source is ON the display shows an asterisks * between the values for Extraction and Injection

3 Foot switch and pedal

When used as a stand-alone unit, pneumatic foot switches control the Vitrex. When used in combination with the OS3 VC830100 base unit, it is controlled by the duallinear pedal.

3.1 Foot-operated switch (stand-alone operation)
The hoses for the pneumatic foot-operated switches INJCT (no. 1), EXTR (no. 2) and AIR (no. 3) can be inserted into the rear of the Vitrex unit. Ensure that the foot-operated switches are not depressed whilst the hoses are being inserted.

3.2 Duallinear pedal (interconnected operation)
In interconnected operation, the INJCT, EXTR and AIR functions can be controlled by the duallinear pedal. See operating instructions VV016011D for the OS3 base unit.

4 Supply connections / power on-off
4.1 Compressed air connection
Connect the compressed air connector K to the compressed air network using a NIST EN 397 air fitting (VX100911).

IMPORTANT!

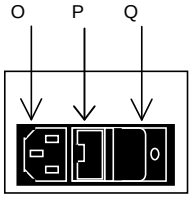
The compressed air supply must have a pressure of 6.5 – 10 bar!

NOTE: The LUM (light) and AIR functions can be operated even without a pressure connection.

4.2 Electrical connection

IMPORTANT!

The mains supply voltage in the operating area must be 100 - 240 V AC / 50 - 60 Hz!



Plug the supplied mains cable into the mains connection socket O (on the rear panel of the unit), and connect to the mains supply socket.

Set the mains switch Q to position I.

As soon as it is switched on, the unit performs an autotest to check the functioning of the circuits, voltages and pressure system.

If no pressure is detected, the message "CHECK COMPRESSED AIR!" appears.

After a successful test, the message "SYSTEM READY!" appears, and the installed software version is displayed in weakly illuminated lettering.

The unit is now ready and can be prepared for the operation.

4.3 Replacing fuses
Press clip on fuse holder P to the right, until it pops out. Use a small screw driver if need be. Fully pull out holder. Insert new fuse and push holder P back in again.

The correct fuse value is printed above the holder P on the rear panel of the unit.

5 Operation
5.1 AIR
Connect an air delivery line with filter (VV690100) or an alternative Oertli original air feed accessory (see Section 11) to the AIR (A) port. Observe the instructions on the packaging note.

IMPORTANT!

Only Oertli original accessories should be used. A filter should always be attached to the AIR port. Accessories must not be re-used!

Press one of the buttons AIR1, AIR2 or AIR3. The stored pressure value and the indicator lamp for the respective memory will light up in the air pressure display field.

Use the arrow button to change the pressure value. The range is 1-120 mmHg, unless otherwise limited in ParaProg.

The air supply can be switched on and off in the following ways:

- With the active (light indicator) AIR1, 2, 3 button
- With the AIR foot switch (pneumatic)
- With the TOP right pedal switch [1)], if used in conjunction with the OS3 base unit
- With the active AIR1, 2, 3 button (light indicator) on the remote controller if used in conjunction with the base unit.

[1)] If specified in ParaProg for the base unit

NOTE: If the Vitrex unit is in standby or System Ready mode, the AIR1 function will be switched on just by activating the foot switch or the TOP right switch.

The display will flash continuously while the air supply is active, and it is possible to change between memories AIR1, AIR2 or AIR3 at any time.

The AIR function can be operated in parallel with all of the other functions of the OS3 system (Vitrex and base unit).

IOP function (only in interconnected operation)
When the IOP button is active (indicator light on), air pressure can be changed using the HEEL switches of the duallinear pedal (stepless, or by changing between AIR 1, 2 and 3, depending on the ParaProg setting). The air pressure is shown in the display for the bottle height (OS3

operating panel), and the corresponding arrow buttons are functional.

The IOP function is used mainly in conjunction with the accessories for active infusion.

Warning tone
An alarm threshold for the pressure value can be defined in ParaProg (Section 7). When the specified pressure value is reached, an alarm tone sounds regardless of memory AIR1, 2 or 3.

Storing values
Press the desired button AIR1, 2 or 3. Set the pressure to the required value using the arrow buttons. Hold down the active button AIR1, 2 or 3 until "VALUE SET" appears. If the button is not depressed long enough, "NOT SET" will appear.

NOTE: When used in conjunction with the OS3 base unit, the value stored will apply only for the surgeon whose number has been entered.

5.2 VISCO

Connect a silicone application set, VV690210 or VV690211 or other Oertli original Visco accessory to the VISCO (B) port. Observe the instructions on the packaging note precisely.

IMPORTANT!

Only Oertli original accessories should be used. Always attach the VISCO connection to an infusion syringe, and never bring it into direct contact with the eye!

INJCT function
Press the INJCT button. The value used last appears in the injection pressure display field (surgeon-specific in interconnected operation). Use the arrow buttons to change the pressure value. The range is 0.05 – 5.0 bar unless otherwise limited in ParaProg (Section 7).

The injection pressure is switched on or off by pressing the pneumatic foot switch (left). The display will flash and an acoustic signal will sound. When used in conjunction with the OS3 base unit, the injection pressure is regulated linearly by moving the duallinear pedal to the left or right.

To exit the INJCT function, press the INJCT button or, in interconnected operation, a function button on the OS3 base unit.

EXTR function
Press the EXTR button. The value used last appears in the extraction vacuum display field (surgeon-specific in interconnected operation). Use the arrow buttons to change the vacuum value. The range is 0.01 – 1.0 bar unless otherwise limited in ParaProg (Section 7).

The extraction vacuum is switched on or off by pressing the pneumatic foot switch (right). The display will flash and an acoustic signal will sound. When used in conjunction with the OS3 base unit, the vacuum value is regulated linearly by moving the duallinear pedal to the left or right.

To exit the EXTR function, press the EXTR button or, in interconnected operation, a function button on the OS3 base unit.

INJCT/EXTR function
Both the INJCT and EXTR functions can be operated simultaneously. Press the INJCT and EXTR buttons to do this. When using the duallinear pedal, INJCT is to the left and EXTR to the right.

NOTE: In interconnected operation with the OS3 base unit, the aspiration function may also be operated during the INJCT and EXTR function. To do this, set the required flow rate (venturi rate) and aspiration vacuum on the base unit. The values used last will appear. To aspirate, move the duallinear pedal to position 2.

5.3 LUM light source

IMPORTANT!

Never operate the light source with the cover open – risk of being dazzled!

Always connect a light instrument to the light output before switching on to avoid being dazzled!

Never use light instruments with other connectors and never push foreign objects into the light output socket.

Reduce the brightness using the rotary knob before switching on.

Connect a light instrument with Oertli original light connector to each of the light outputs LUM1 and LUM2.

The VX100940 adapter can be used to connect disposable light instruments.

The light source is suitable for both disposable and autoclavable light instruments.

Insert the light instrument into the connection socket until fully engaged.

Switch on the lamps with the LUM1 and LUM2 buttons. To switch off, press the respective button again. The cooling fan will continue to run for a time.

The desired brightness can be set smoothly using the rotary knobs for light dimming. The two light sources are independent of each other.

NOTE: Hot lamps must be allowed to cool down before they can be switched on again. The cooling time is around 30 seconds. A message will appear if an attempt is made to switch on the lamp again within this period of time.

NOTE: If a lamp begins to flicker during operation, it has reached the end of its service lifetime. The lamp must be replaced before the next operation.

NOTE: if both lamps fail to light up, switch the unit off for at least 15 seconds. Then try again to light the lamps.

5.3.1 Changing lamps

If a lamp does not light up after frequent attempts to do so or does not light up at all within one minute, it has reached the end of its service life and must be replaced.

- Allow the unit to cool until the fan switches off, then switch off the mains switch Q.
- Remove the middle screw from the sliding cover.
- Open the sliding cover on top of the unit in the direction of the arrow.
- Remove the clamping screw next to the socket and separate the plug halves.
- Pull out the socket together with the lamp and insert a new lamp.
- Insert the clamping screw and connect the plug halves together.

IMPORTANT!

- Risk of burns
- Do not touch the metal halide lamps with your bare hand! Hold the lamp by the metal socket only. Use only original VV300004 lamps.

6 ParaProg settings

Several important basic settings can be entered in the ParaProg. These settings only affect the Vitrex unit, and have nothing to do with the ParaProg settings for the OS3 base unit. However, if the Vitrex unit is being used in conjunction with the OS3 base unit, the ParaProg settings will apply only for the surgeon selected in the base unit.

IMPORTANT!

For ParaProg settings in interconnected operation, it is essential that the surgeon number in the base unit is observed!

To access the ParaProg function, switch off the Vitrex unit at the mains switch Q Then press and hold down the INJCT button whilst switching on the mains switch Q again. Release the INJCT button as soon as "ParaProg" is displayed.

To page forward in the program, press the ↓ button. Alternatively, the arrow buttons beneath AIR can be used to page forwards or backwards.

The ParaProg parameters are defined in the VV016032D appendix. Make sure that they agree with the installed software.

The respective parameter appears in the AIR display field. Selectable options are shown in the INJCT field. The Illuminated value is the one previously selected; the flashing value may be selected by pressing the ↵ -button.

To exit ParaProg, press the AIR1 function button.

7 System communication

7.1 Visual displays

Selected, stored and current values and important information about the status of the unit are indicated by light displays on the control panel. Warnings and instructions appear in the language selected in ParaProg. See Section 7.

7.2 Acoustic signals

The unit uses acoustic signals to inform you about the generation of vacuum and pressure.

INJCT pressure: slow repeating beep tone
EXTR vacuum: slow repeating high/low acoustic signal

Volume control

The volume can be set between 0 - 100 % in ParaProg. The volume is not surgeon-specific when used in combination with the OS3 base unit.

7.3 Voice confirmation

If the unit is being operated in conjunction with the OS3 base unit, the voice confirmation function of the OS3 base unit will also include the Vitrex unit. See operating instructions VV016011D for the OS3 base unit for detailed information.

8 Choice of set values

Every surgeon develops his own preferred operating technique, which also requires specific set values for the various stages of the operation.

The OS3 unit enables a high level of compatibility with these individual requirements.

The unit is supplied with the values set during the last trial or internal works test. These values are certainly not recommended or suggested values. The correct choice of equipment settings is the responsibility of the surgeon!

Please also note that set values cannot necessarily be transferred from other makes of operating equipment to the OS3 unit.

As a general principle, we recommend that you work initially with moderate set values.
Our sales consultants will be pleased to advise you on the basis of our experience during the trial and induction period.

9 Cleaning and sterilisation instructions

IMPORTANT!

Under no circumstances may accessories for air supply, active infusion and visco application be reused!

9.1 Cleaning

Autoclavable light instruments must be immersed in BSS or distilled water and thoroughly rinsed immediately after the operation!
The cleaning instructions supplied with the instruments should be strictly observed!

Use only distilled or de-ionised water, neutral detergents and a soft lint-free cloth or a soft sponge!
Ensure that all instruments are free of blood, tissue and impurities caused by saline deposits or other substances.
Rinse carefully and thoroughly with distilled water, and carefully clean with compressed air.
Do not use oxygen or other gases!

9.2 Sterilisation

Steam sterilisation is the prescribed method for light instruments. ETO sterilisation is not recommended, and gamma sterilisation is not permitted owing to the instability of the materials!

IMPORTANT!

The user is responsible for the proper application of sterilisation methods including precautions taken to ensure bacteriological safety.

After cleaning (as described in Section 10.1), the instruments must be sterilised in the autoclave with the supporting air extraction device.
The recommended values are: temperature 134°C - 138°C, minimum cycle duration of 3 minutes.
When the instruments are removed from the sterilisation unit, they should be cooled to room temperature before operating.

IMPORTANT!

Instruments must always be sterilised before every use!

10 Accessories and replacement parts

IMPORTANT!

The use of accessories other than those listed, or of other converters and cables may lead to increased interference emission or reduced interference immunity of the unit or system!

IMPORTANT!

Accessories, converters and cables are listed in the following table for which the manufacturer guarantees EMC compatibility!

Unit accessories

VC830100	OS3 base unit
VE830001	Unit trolley with infusion pole drive
VE830010	Programmable duallinear pedal
VE830020	Remote control with illumination
VX100940	Light adapter for disposable leads
VX100907	Pneumatic foot switch AIR
VX100908	Pneumatic foot switch INJCT/EXTR (VISCO)
VX100911	Pressure hose with NIST air connection
VX100912	OS3/Vitrex pneumatic connection cable
VX100913	OS3/Vitrex COM connection cable
VV300004	Replacement metal halide lamps
VX520010	3.15 AT fuses, high breaking capacity

Consumable material, AIR/VISCO (disposable)

VV690100	Air delivery line with filter, pack of 10
VV690110	Air application set for IOP control, anterior
VV690111	Air application set for IOP control, posterior
VV690210	Silicone application set, 20 cc, pack of 10
VV690211	Silicone application set, Opsia, pack of 10

Consumable material, light (disposable)

VV300101	Endo illuminator, straight, pack of 10, microconnection
VV300131	Endo illuminator, 30°, pack of 10, microconnection
VV300201	Endo illuminator with microhook, pack of 10, micro-connection

Light instruments, autoclavable

VE201728	Endo illuminator with diathermy, "plug-on"
VE301005	Endo illuminator with microhook, 2 m cable
VE302003	Light sleeve for SDS instruments, 1.6 mm
VE302004	Light sleeve for SUS instruments, 1.6 mm
VE308130	Endo illuminator, 30°, 2 m cable
VE308160	Endo illuminator, 60°, 2 m cable
VE308190	Endo illuminator, straight, 2 m cable

11 Authorised service centres

Switzerland (Manufacturer)
Oertli Instrumente AG
Hafnerwisenstr. 4
CH–9442 Berneck
Phone: +41–71–7474200

Germany
Domilens GmbH
Holsteiner Chaussee 303a
D–22457 Hamburg
Phone: +49–40–5598800

Austria
Mositech GmbH
Schwefel 93
A–6850 Dornbirn
Phone: +43–5572–34534

Information about other service centres can be obtained from the manufacturer.

Authorised representative in the EU
Germany
Oertli Instrumente GmbH
Magnolienweg 14
D–63741 Aschaffenburg

12 Technical data

Supply pressure*	Air 6.5 - 10 bar, max. 25l/min NIST EN-739 connection
Supply voltage	100 – 240 V AC
Supply voltage frequency	50 – 60 Hz
Power consumption	320 VA
Fuses	3.15 AT, high breaking capacity
Operating mode	continuous
Application parts	non-electrically powered
Protection class	I
CE classification	IIb
Visco injection	0.05 - 5 bar ±0.2 bar
Visco extraction	0.01 - 1 bar ±0.05 bar
Air pump	1 - 120 mmHg ±10 mmHg

Light	Metal halide 24 V/21 W 2 x 1460 Lumen
Noise emission	< 70 dB (A)
Dimensions	380 x 110 x 340 mm (W/H/D)
Weight	8.7 kg
Transport and storage conditions	Temperature 20°C - +55°C Atmos. pressure 500hPa - 1060hPa Relative humidity 10% - 95% non-condensing
Operating conditions	Temperature 10°C - 35°C Atmos. pressure 700hPa - 1060hPa
Relative humidity	20% - 80% non-condensing

*If there is no compressed air connection, the INJCT and EXTR functions cannot be operated

13 Overview of messages, warnings and error messages

Pressure deviation
The actual value deviates considerably from the desired value.
Automatic safety venting.

No pressure
Pressure at the compressed air connection is too low.
Check supply pressure (min. 6.5 bar).

Not set.
Values were not stored.

System ready
The autotest has been successfully completed.

Values set
Values were stored.

Set values
Values will be stored.

Temperature too high
Allow the light to cool.

Replace lamp 1
Lamp 1 is defective, replace it.

Replace lamp 2
Lamp 2 is defective, replace it.

Call Service Error 101
Call service (internal voltages defective).
Unit cannot be operated.

Adjust Unit Error 102
Call service (pressure measurement incorrect).
Unit cannot be operated.

Extr Deviation Error 103
Pressure instead of vacuum.
Call service.

HW Lum Error 104
Incorrect light source set.
Call service.

14 Explanation of symbols

	Use only mains fuses with the specified value
	Risk of burns!
	Follow the operating Instructions
	Dangerous voltages. Do not open the unit!
	Footswitch connection
	Grounding pin
	Operating Instructions
	WEEE – have the appliance disposed of correctly
COM	Connection for communication with OS3 base unit

15 Calibration and maintenance

The unit requires the following calibration and maintenance:

Yearly calibration:

- Adjustment of the pressure sensor as described in the service manual

Yearly maintenance:

- Checking of electrical cables (instrument and power leads) for signs of wear and tear, and replacement as necessary.

16 Disposal

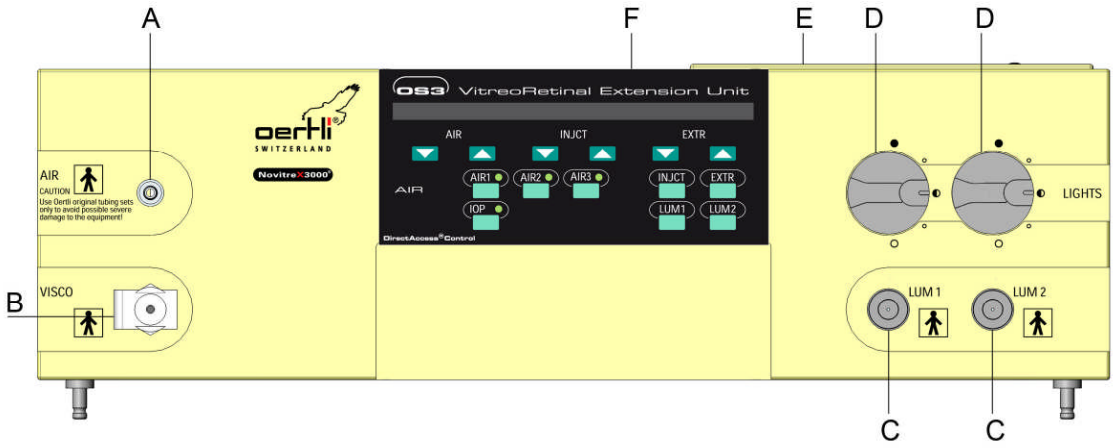
This unit should be disposed of in accordance with local regulations for the disposal of electronic equipment, or it should be returned to the manufacturer for disposal.

Items designed for single use should be disposed of in accordance with local regulations for the disposal of contaminated medical waste.

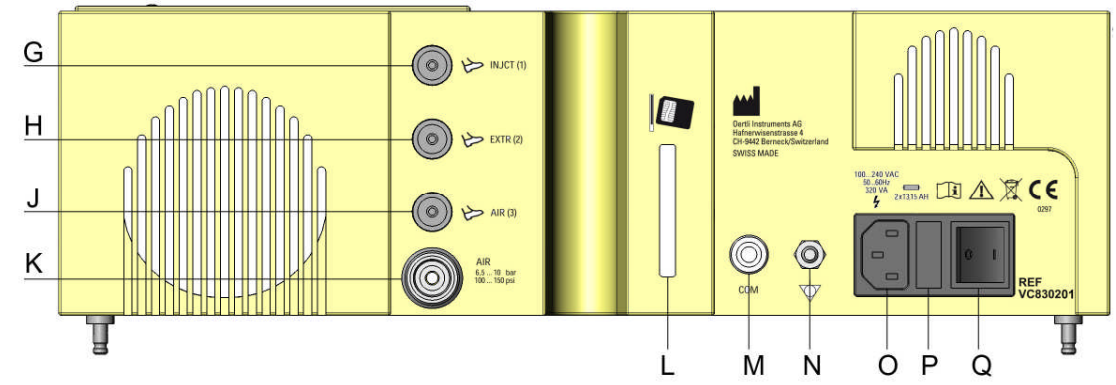
Instruments for repair should be cleaned and sterilised prior to their return to the service centre.

17 OS3 Vitrex VC830201, Overview

Front view



Rear view



A Air hose connection (air pump)
B Visco application set connection (INJCT/EXTR)
C Light cable connections (Oertli standard)
D Rotary knobs for light dimming
E Sliding cover for replacing lamps
F Control panel
G Connection for injection footswitch
H Connection for extraction footswitch
J Connection for air footswitch
K Compressed air connection (see service manual)
L Slot for smart card (see service manual)
M Connection for data cable to the base module
N Grounding pin
O Mains connection socket
P Fuse holder
Q Mains switch

Table 201:

Guidelines and manufacturer's declaration – electromagnetic compatibility		
The unit is intended for operation in the electromagnetic environment described below. The customer or the user of the unit should ensure that it is used in such an environment.		
Emission measurement	**Conformity**	**Electromagnetic environment - guidelines**
HF emissions according to CISPR 11	Group 1	The unit uses HF energy exclusively for its own internal functions. Its HF emission level is therefore very low and it is unlikely that adjacent electronic equipment will be affected.
HF emissions according to CISPR 11	Class B	The unit is intended for use in all facilities including residential areas and those directly connected to public supply networks that also supply residential buildings.

Table 202:

Guidelines and manufacturer's declaration – electromagnetic immunity			
The unit is intended for operation in the electromagnetic environment described below. The customer or the user of the unit should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6kV contact discharge ± 8kV air discharge	± 6kV contact discharge ± 8kV air discharge	Floor should be made of wood or concrete or covered by ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical interference variables/bursts according to IEC 61000-4-4	± 2kV for mains cable ± 1kV for input and output cables	± 2kV for mains cable ± 1kV for input and output cables	The quality of the supply voltage should be equivalent to that in a typical commercial or hospital environment.
Surge voltages (Surges) according to IEC 61000-4-5	± 1kV voltage external conductor – external conductor ± 2kV voltage external conductor – earth	± 1kV voltage external conductor – external conductor ± 2kV voltage external conductor – earth	The quality of the supply voltage should be equivalent to that in a typical commercial or hospital environment.
Voltage drops, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5 % U_T for ½ cycle (> 95 % drop) 40 % U_T for 5 cycles (60 % drop) 70 % U_T for 25 cycles (30 % drop) < 5 % U_T for 5 sec. (> 95 % drop)	< 5 % U_T for ½ cycle (> 95 % drop) 40 % U_T for 5 cycles (60 % drop) 70 % U_T for 25 cycles (30 % drop) < 5 % U_T for 5 sec. (> 95 % drop)	The quality of the supply voltage should be equivalent to that in a typical commercial or hospital environment.
Magnetic field at the mains supply frequency according to IEC 61000-4-8	3 A/m	30 A/m	Magnetic fields at the rated frequency should be equivalent to the typical values found in commercial and hospital environments.
NOTE: U_T is the mains AC voltage before application of the test level			

Table 204:

Guidelines and manufacturer's declaration – electromagnetic immunity

The unit is intended for operation in the electromagnetic environment described below. The customer or the user of the unit should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Conformity level	Electromagnetic environment - guidelines
			Portable and mobile radio devices are not used at a distance closer to the unit including its cables than the recommended safe distance calculated by means of an equation appropriate for the transmission frequency. **Recommended safe distance:**
Conducted HF interference variables according to IEC 61000-4-6	3 V eff 150 kHz to 80 MHz	10 V eff	$d = 0.35\sqrt{P}$
Radiated HF interference variables according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35\sqrt{P}$ 80MHz to 800MHz $d = 0.70\sqrt{P}$ 800MHz to 2.5GHz
			Where *P* is the rated power of the transmitter in Watts (W) according to the transmitter manufacturer's specifications and *d* is the recommended safe distance in metres (m). The field strength of all stationary radio transmitters is less than the conformity level[b] for all frequencies according to a local examination[3]. Interference is possible in the vicinity of equipment bearing the following symbol.

NOTE 1: The higher value applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and persons.

[a] The field strength of stationary transmitters, e.g. base stations for radio telephones and mobile agricultural broadcast services, amateur radio stations, AM and FM radio and television transmitters cannot be precisely determined theoretically in advance. In order to determine the electromagnetic environment resulting from stationary transmitters, an examination of the location is recommended. If the field strength determined at the location of the unit exceeds the conformity level stated above, the unit must be observed with regard to its normal operation at each place of use. If unusual performance characteristics are observed it may be necessary to take additional measures, such as realigning or moving the unit.

[b] The field strength should be smaller than 10 V/m above the frequency range from 150 kHz to 80 MHz.

Table 206:

Recommended safe distances between portable and mobile HF telecommunication devices and the unit

The unit is intended for operation in the electromagnetic environment described below, in which the HF interference variables are controlled. The customer or the user of the unit can help to avoid electromagnetic interference by maintaining the recommended minimum distance between portable and mobile HF telecommunication devices (transmitters) and the unit as given in the table below according to the maximum output power of the communication device.

Rated power of the transmitter (P) W	**Safe distance in metres depending on the transmission frequency**		
	150kHz to 80MHz $d = 0.35\sqrt{P}$	**80MHz to 800MHz** $d = 0.35\sqrt{P}$	**800MHz to 2.5GHz** $d = 0.70\sqrt{P}$
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters whose maximum rated power is not given in the above table, the recommended safe distance d in metres (m) can be determined using the equation given in the respective column, where P is the maximum rated power of the transmitter in Watts (W) according to the transmitter manufacturer's specifications.

NOTE 1 The higher value applies at 80 MHz and 800 MHz.

NOTE 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and persons.